IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICANT	: Jackowski *et al.*
INVENTION	:**Fibronectin Biopolymer Markers Indicative Of Type II Diabetes**
SERIAL NUMBER	: 09/991,796
FILING DATE	: November 23, 2001
EXAMINER	: Chernyshev, Olga N.
GROUP ART UNIT	: 1646
OUR FILE NO.	: 2132.109

CERTIFICATE UNDER 37 CFR 1.8(a)
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 on 9-16-2003

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DECLARATION UNDER 37 CFR § 1.132

I, Dr. George Jackowski, do hereby declare as follows:

1. I am Chief Executive Officer and Chief Science Officer of Syn-x Pharma Inc., assignee in the application entitled **"Fibronectin Biopolymer Markers Indicative Of Type II Diabetes"**, having U.S. Application Serial No. 09/991,796, filed November 23, 2001.

2. In the Office Action mailed on June 16, 2003, claims 1 and 2 (as originally presented) were rejected under 35 U.S.C. 112, first paragraph because the claimed invention allegedly contains subject matter which was not described in the specification in such

a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner states that the invention is directed to a biopolymer marker of SEQ ID NO:1 or SEQ ID NO:4 or at least one analyte thereof useful in indicating at least one particular disease, for example, Type II Diabetes. The Examiner asserts that the specification fails to provide any guidance on how to use the disclosed peptides (SEQ ID NO:1, SEQ ID NO:4 and analytes thereof) as markers or indicators of any disease, including Type II Diabetes. The Examiner is particularly concerned with an alleged lack of controls in the experiments.

3. This declaration is submitted in order to clarify the use of controls in the experiments disclosed in the specification.

4. There are no conventional controls applied in the methods of the instant invention. Both samples from diseased patients and samples from healthy patients are separated by polyacrylamide gel electrophoresis. The gel is then examined in order to identify differences in the bands appearing in diseased and healthy patients. The bands, which differ between healthy and diseased patients, are excised and purified from the gel. A determination of upregulation, downregulation, presence and/or absence of the proteins present in the bands is assessed by sample wherein they appear, for example, the claimed peptide fragments were identified and excised from bands which appeared lighter in the diseased sample as compared with the healthy sample, indicating a decreased amount of protein expression or protein degradation in the diseased

samples. Thus, this is considered to be downregulation of the protein in the disease sample as compared to the higher level of expression of the protein in the healthy sample. This comparison between two physiological states as evidenced by the bands appearing on the gel represents an inherent control in the experiment. The claimed protein fragments excised from the band appearing in the diseased sample are sequenced and identified through the application of mass spectrometric techniques. Since the band appeared darker in the healthy sample, the corresponding lighter band in the diseased was chosen for excision and sequencing. It is standard laboratory practice to sequence peptides by mass spectrometry and identify the peptides based upon known sequences available in databases; thus sequencing and comparison of control peptides is not required. One of ordinary skill in the art would be familiar with these standard protocols of mass spectrometry.

The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application or any patent issuing thereon.

Sept 15 2003.
Date

George Jabkowski

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